

K073353

### 510(k) SUMMARY

**DO-ALL Dental Handpiece Lubricant**  
**ProDrive Systems Inc.**

OEC - 7 2007

**Owned by:**

ProDrive Systems Inc.  
812 Commerce Drive  
Ogdensburg, NY 13669  
USA

**Contact Person:**

Clive Hooton, Vice President Quality  
ProDrive Systems Inc.  
812 Commerce Drive  
Ogdensburg, NY 13669  
USA

**Date of Summary:**

October 15, 2007

**Device Name:**

Proprietary Name:	DO-ALL Dental Handpiece Lubricant
Common Name:	dental handpiece lubricant
Classification Name:	Handpiece, Air-powered, Dental
Product Code:	EFB ("Dental handpiece and accessories", 21CFR 872.4200)

**Predicate Device:**

Proprietary Name:	ClearView Dental Handpiece Lubricator and Lubricant
510(k) Number:	K070297
Product Code:	EFB

***Description of Device:***

DO-ALL is a lubricant designed for use with air-powered dental handpieces. The product is intended to be used prior to handpiece sterilization to lubricate the moving parts inside of the air-powered turbine. The lubricant is not intended to come into contact with the patient and has no therapeutic function.

The performance testing presented in the body of this submission illustrates that DO-ALL performs as well as the predicate device in head-to-head comparisons. The product is found to withstand repeated cycles of use/sterilization without degradation of the performance of the dental handpiece.

Dental handpieces lubricated with DO-ALL were shown to meet or exceed all of the applicable performance standards outlined in ISO 7785-1:1997(E). Extensive testing illustrated that after 250 use/sterilization cycles the handpiece continued to meet all performance requirements.

DO-ALL has been shown to be suitable for lubrication of dental handpieces. Based on its composition and comparisons to the predicate device, it is considered to be safe under normal usage and has no expected hazards.

***Intended Use of Device:***

DO-ALL Dental Handpiece Lubricant is intended to be used to lubricate air driven dental handpieces, turbines and air motors for the purpose of maintenance prior to sterilization.

***Comparison of Technological Characteristics to Predicate Device:***

The following table compares the features of DO-ALL Dental Handpiece Lubricant to the Predicate Device:

**Table 1: Substantial Equivalence Table**

TECHNOLOGICAL CHARACTERISTIC	COMPARISON TO PREDICATE
Intended use	Identical
Indications for use	Identical
Target population	Identical
Anatomical sites	Identical
Where used	Identical
Energy used and/or delivered	Identical
Human factors	Identical
Design	Identical
Performance	Similar
Standards met	Identical
Materials	Similar
Biocompatibility	Identical
Compatibility with environment and other devices	Identical
Sterility	Identical
Electrical safety	Identical
Mechanical safety	Identical
Chemical Safety	Identical
Thermal safety	Identical
Radiation safety	Identical

***Conclusions Drawn from Technical Comparison:***

DO-ALL Dental Handpiece Lubricant is essentially the same as the predicate device in terms of its intended use, operating principles and materials.

Use of the DO-ALL Dental Handpiece Lubricant has no deleterious effect on the ability of Dental Handpieces to meet the relevant requirements of the ISO 7785-1:1997(E) standard and the FDA Guidance Document on Dental Handpieces, which include testing and performance limits on the following characteristics:

- Extraction force
- Torque
- Eccentricity
- Speed
- Resistance to corrosion
- Noise level
- Reprocessing
- Stall torque

The performance testing of Dental Handpieces lubricated with DO-ALL indicates that they function as well as Dental handpieces lubricated with the predicate device in all aspects examined.

Therefore, we conclude that the DO-ALL Dental Handpiece Lubricant is both safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 7 2007

ProDrive Systems, Incorporated  
C/O Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, Minnesota 55313

Re: K073353

Trade/Device Name: DO-ALL Dental Handpiece Lubricant  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece and Accessories  
Regulatory Class: I  
Product Code: EFB  
Dated: November 28, 2007  
Received: November 29, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

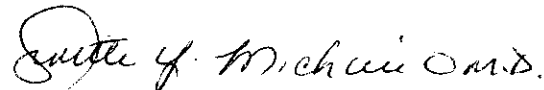
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Chiu Lin, Ph.D.", is written over the typed name.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: DO-ALL Dental Handpiece Lubricant

Indications For Use: To be used to lubricate air driven dental handpieces, turbines and air motors for the purpose of maintenance prior to sterilization.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

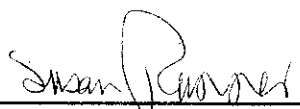
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K078353